

March 5, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Emilex

DP Barcode: D313000

Reg. No. Or File Symbol: 5813-IL

Manufacturing-use []

End-use Product [X]

TO: Wallace Powell, EPA Work Assignment Manager

FROM: Joan Cuddeback, CSC/DynCorp Work Assignment Manager

This is a review of the following Product Chemistry 830 Series study packages provided to CSC/DynCorp for preliminary review:

Physical and Chemical Characteristics (MRID 464524-01)

830 Series, Part A: 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1620 (Description of Production Process), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), 830.1700 (Preliminary Analysis), 830.1750 (Certified Limits), 830.1800 (Enforcement Analytical Methods), and 830.1900 (Submittal of Sample).

830 Series, Part B: 830.6302 (Color), 830.6303 (Physical State), 830.6304 (Odor), 830.6313 (Stability to Normal and Elevated Temperatures, Metals and Metal Ions), 830.6314 (Oxidation/Reduction; Chemical Incompatibility), 830.6315 (Flammability/Flame Extension), 830.6316 (Explosibility), 830.6317 (Storage Stability), 830.6319 (Miscibility), 830.6320 (Corrosion Characteristics), and 830.6321 (Dielectric Breakdown Voltage), 830.7000 (pH), 830.7050 (UV/Vis Absorption), 830.7100 (Viscosity), 830.7200 (Melting Point/Melting Range), 830.7220 (Boiling Point/Boiling Range), 830.7300 (Density/Relative Density/Bulk Density), 830.7370 (Dissociation Constants in Water), 830.7520 (Particle Size, Fiber Length, and Diameter Distribution), 830.7550 (n-Octanol/Water Partition Coefficient: Shake Flask Method), 830.7560 (n-Octanol/Water Partition Coefficient: Generator Column Method), 830.7570 (n-Octanol/Water Partition Coefficient: Estimation by Liquid Chromatography), 830.7840 (Water Solubility: Column Elution Method; Shake Flask Method), 830.7860 (Water Solubility: Generator Column Method), and 830.7950 (Vapor Pressure).

Product Formulation

Active Ingredients:

% by wt.:

Sodium Hypochlorite* 0.0095%

*From [REDACTED]

- The applicant has provided a justification for not being required to satisfy the requirements of the following Part A product chemistry data requirements: 830.1620 (Description of Production Process), and 830.1700 (Preliminary Analysis) and 830.1900 (Submittal of Samples) as Emil is an end-use product formulated from registered manufacturing use products, by simple mixing.
- The label ingredient statement, which lists the nominal concentration, is consistent with the CSF and conforms to recommendations of PR Notice 91-2, with the exception that, while the applicant has declared the sodium hypochlorite as an active ingredient, it has not declared the equivalent available free chlorine as a sub-statement.

830 Series, Part B:

- The applicant has provided a Self-Certification Statement for the Physical/Chemical Properties (EPA Form 8570-37) to satisfy Part B data requirements.
- The following Part B product chemistry data requirements seem to be complete: 830.6303 (Physical State), 830.7000 (pH), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density).
- 830.6314 (Oxidation/Reduction: Chemical Incompatibility) data requirements have been referenced in the Data Matrix form as having been previously submitted in MRID 432329-01 (a Clorox Company study).
- The applicant has provided a justification for not being required to satisfy the requirements of the following guidelines: 830.6315 (Flammability/Flame Extension), 830.6316 (Explosibility), 830.6319 (Miscibility), 830.6321 (Dielectric Breakdown Voltage) and 830.7520 (Particle Size, Fiber Length and Diameter Distribution) as the product does not contain oxidizing or reducing agents, has no flammable or explosive ingredients, is not to be diluted with petroleum solvents, will not be used around electrical equipment, and is neither powdered-type nor a fibrous product.
- Also, the applicant has provided a justification for not being required to satisfy the requirements of the following guidelines: 830.6302 (Color), 830.6304 (Odor), 830.6313 (Stability to Normal and Elevated Temperatures, Metals and Metal Ions), 830.7050 (UV/Vis Absorption), 830.7200 (Melting Point/Melting Range), 830.7220 (Boiling Point/Boiling Range), 830.7370 (Dissociation Constants in Water), 830.7550 (n-Octanol/Water Partition Coefficient: Shake Flask Method), 830.7560 (n-Octanol/Water Partition Coefficient: Generator Column Method), 830.7570 (n-Octanol/Water Partition Coefficient: Estimation by Liquid Chromatography), 830.7840 (Water Solubility: Column Elution Method; Shake Flask Method), 830.7860 (Water Solubility: Generator Column Method), and 830.7950 (Vapor Pressure) as the product is end-use, does not consist solely of the technical grade of the active ingredient, and is not produced by an integrated

126

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒
- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes ☐ No ☐ Not applicable ☒

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes ☒ No ☐

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes ☐ No ☒
- 1.0% or more of methyl alcohol: Yes ☐ No ☒
- Sodium nitrite at any level: Yes ☐ No ☒
- a toxic List 1 inert at any level: Yes ☐ No ☒
- arsenic in any form: Yes ☐ No ☒

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?

Yes ☒ No ☐ Not applicable ☐ *Flammability and Explodability N/A.
See FINDINGS.*

6.

PRODUCT CHEMISTRY (830 Series, Part A)

| 6a. Data Requirements | Acceptance of Information | MRID No. |
|---|---------------------------|--------------|
| 830.1550 ¹ Product Identity | | 464524-01 |
| 830.1600 Description of Materials | | 464524-01 |
| 830.1620 Production Method ² | | 464524-01 NA |
| 830.1650 Formulation process ³ | | 464524-01 |
| 830.1670 Formation of impurities ⁴ | | 464524-01 |
| 830.1700 Preliminary Analysis ⁵ | | 464524-01 NA |
| 830.1750 Certified Limits ⁶ | | 464524-01 |
| 830.1800 Analytical Method ⁷ Sodium hypochlorite by titrometric determination | | 464524-01 |

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

108

Physical and Chemical Characteristics (Series 830, Part B)

| 6b. <u>Physical/Chemical Properties*</u> | Acceptance of data | Value or qualitative description | MRID No. |
|--|--------------------|--|----------------------|
| 830.6303 Physical state | | liquid | 464524-01 |
| 830.7200 Melting point | | NA. Product is a liquid. | 464524-01 |
| 830.7300 Density/Relative density/bulk density | | 1.00 g/mL (8.34 lb/gal) (Ref. Clorox SOP 000-032-00) | 464524-01 |
| 830.7000 pH ¹ | | 7.47 (Ref. Clorox SOP 001-02-03) | 464524-01 |
| 830.6314 Oxidation/Reduction | | See previously submitted MRID. | 432329-01 |
| 830.6315 Flammability | | NA. Product does not contain combustible liquids. | 464524-01 |
| 830.6317 Storage stability | | NA. The stability study is ongoing; the applicant has requested that the 1-year study be made a condition of registration. | 464524-01 Ongoing |
| 830.7100 Viscosity | | 0.73 cps at 40°C and 1.1 cps at 20°C by Wells-Brookfield Cone/Plate Viscometer. (Ref. Clorox SOP 001-175-00) | 464524-01 |
| 830.6319 Miscibility ² | | NA. The product is not an emulsifiable liquid and it is not to be diluted with petroleum solvents. | 464524-01 |
| 830.6320 Corrosion Characteristics | | NA. The corrosion study is ongoing; the applicant has requested that the 1-year study be made a condition of registration. | 464524-01 Ongoing |
| 830.6321 Dielectric breakdown | | NA. Product is not intended to be used around electrical equipment. | 464524-01 |

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25°C.

¹ If product is dispersible with water

² If product is an emulsifiable liquid